



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As the below named inventor, I hereby declare that:

My residence, post office address and citizenship is as stated below next to my name;

I believe that I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

NUCLEIC ACIDS AND PROTEINS FROM GROUP B STREPTOCOCCUS

RECEIVED
AUG 14 2003

the specification of which: ☐ is attached hereto.

☒ was filed on: March 6, 2002

as Application No.: 10/091,007

and was amended on: _____ (if applicable).

OFFICE OF PETITIONS

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56.

And I hereby authorize and request our agents, Brobeck, Phleger & Harrison LLP, whose address is set forth below, to insert above, the filing date and application number of said application when known.

Prior Foreign Application(s)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Country	Application Number	Date of Filing (day, month, year)	Date of Issue (day, month, year)	Priority Claimed	
Great Britain	9921125.2	7 September, 1999		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

Prior Provisional Application(s)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

Application Number	Date of Filing (day, month, year)

RECEIVED

JUL 31 2003

TELEPHONE CENTER 1600/2900

Prior United States Application(s)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Number	Date of Filing (day, month, year)	Status – Patented, Pending, Abandoned
PCT/GB00/03437	September 7, 2000	Pending

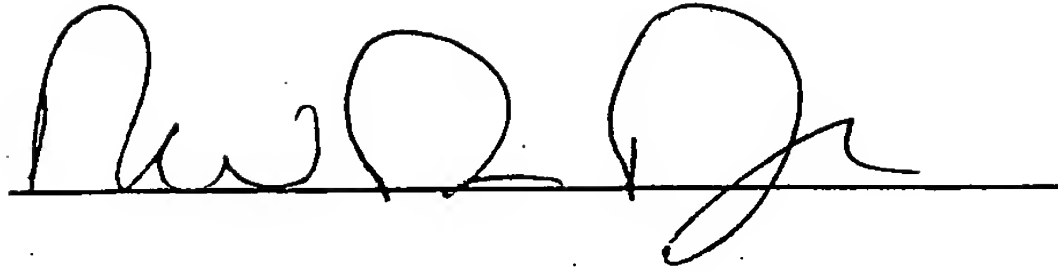
And I hereby appoint, both jointly and severally, as my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith the following attorneys, their registration numbers being listed after their names:

Rodger L. Tate, Registration No. 27,399; Anthony W. Shaw, Registration No. 30,104; Cono A. Carrano, Registration No. 39,623; Laurence H. Posorske, Registration No. 34,698; Robert A. King, Registration No. 42,738; Craig L. Puckett, Registration No. 43,023; and Trevor Q. Coddington, Registration No. 46,633.

All correspondence and telephone communications should be addressed to: Brobeck, Phleger & Harrison LLP; Intellectual Property Department; 1333 H Street, N.W.; Suite 800; Washington, DC 20005; telephone number (202) 220-6000; facsimile number (202) 220-5200, which is also the address, telephone and facsimile numbers of each of the above listed attorneys.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature



Date 18 April 2002

Full Name of
First Inventor:

LE PAGE
(Family Name)

Richard William
(First Given Name)

Falla
(Second Given Name)

Citizenship:

United Kingdom

Residence:

Cambridge, United Kingdom

Post Office
Address:

c/o Gonville & Caius College,
Cambridge CB2 1TA, United Kingdom

Signature

Date _____

Full Name of
First Inventor:

WELLS,
(Family Name)

Jeremy
(First Given Name)

Mark
(Second Given Name)

Citizenship:

United Kingdom

Residence:

Norwich, United Kingdom

Post Office
Address:

Institute of Food Research, Norwich Laboratory
Norwich Research Park
Colney, Norwich NR4 7UA United Kingdom

Signature

Date _____

Full Name of
Third Inventor:

HANNIFY
(Family Name)

Sean
(First Given Name)

Bosco
(Second Given Name)

Citizenship:

United Kingdom

Residence:

Norwich, United Kingdom

Post Office
Address:

c/o Institute of Food Research
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☒ was filed on: March 6, 2002
as Application No.: 10/091,007
and was amended on: _____ (if applicable).

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Prior United States Application(s)

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Signature _____

Date _____

Full Name of
First Inventor:

LE PAGE
(Family Name)

Richard William
(First Given Name)

Falla
(Second Given Name)

Citizenship:

United Kingdom

Residence:

Cambridge, United Kingdom

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c/o Gonville & Caius College,
Cambridge CB2 1TA, United Kingdom

Signature _____

Date 15th May 2002

Full Name of
First Inventor:

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(Family Name)

Jeremy
(First Given Name)

Mark
(Second Given Name)

Citizenship:

United Kingdom

Residence:

Norwich, United Kingdom

Post Office
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Institute of Food Research, Norwich Laboratory
Norwich Research Park
Colney, Norwich NR4 7UA United Kingdom

Signature _____

Date 15th May 2002

Full Name of
Third Inventor:

HANNIFY
(Family Name)

Sean
(First Given Name)

Bosco
(Second Given Name)

Citizenship:

United Kingdom

Residence:

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Post Office
Address:

c/o Institute of Food Research
Norwich Laboratory
Norwich Research Park
Colney, Norwich, NR4 7UA United Kingdom

Office Action Summary

Application No.

10/091,007

Applicant(s)

William et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 6, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

Restriction

- 1) Claims 1-24 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1- 3, 11-13 and 22, drawn to a Group B *Streptococcal* protein or polypeptide shown in Figure 1, or fragments or derivatives thereof, classified in class 530, subclass 350.
 2. Claims 4-6, 8, 14-16 and 23, drawn to a DNA sequence set out in Figure 1 and a vector comprising the same, classified in class 536, subclass 23.7.
 3. Claims 9 and 21, drawn to an antibody capable of binding to a protein or polypeptide as defined in Figure 1, classified in class 530, subclass 387.9.
 4. Claim 7, drawn to a method of use of a vector comprising a DNA sequence set out in Figure 1, classified in class 435, subclass 320.1
 5. Claim 9, drawn to a process of producing a Group B *Streptococcal* protein or polypeptide shown in Figure 1 by expression in a host cell, classified in class 435, subclass 71.1
 6. Claim 17, drawn to a method of using a composition comprising DNA sequence set out in Figure 1, classified in class 424, subclass 234.1
 7. Claim 18, drawn to a method of detecting Group B streptococcus using an antibody capable of binding to a protein or polypeptide as defined in Figure 1, classified in class 435, subclass 7.1
 8. Claim 19, drawn to a method of detecting Group B streptococcus using a

protein or polypeptide as defined in Figure 1, classified in class 435, subclass 7.34

9. Claim 20, drawn to a method of detecting Group B streptococcus using a DNA sequence as defined in Figure 1, classified in class 435, subclass 6

10. Claim 24, drawn to a method of inactivating a protein or polypeptide shown in Figure 1, classified in class 530, subclass 427

4) Inventions 1-10 are patentably distinct from one another. Inventions 1-3 are drawn to distinct products which differ from one another structurally, biologically and/or immunogenically. The various claimed sequences or products require separate structural searches that are non-coextensive. Inventions 4-10 are drawn to distinct methods which differ from one another in method steps, parameters, reagents or products used, and the ultimate goals accomplished. The product of invention 1 is not required to practice the methods of inventions 4, 6, 7 and 9. Similarly, the product of invention 2 is not required to practice the methods of inventions of 7, 8 and 10. The product of invention III is not required to practice the methods of 4-6 and 8-10.

5) After electing one of the above-identified inventions, Applicants should further elect one of the recited protein or DNA sequences, or one of the antibodies specific to one of the recited protein sequences for examination.

6) Inventions 1, 2 and 3 respectively, and inventions 8 and 9, inventions 4-6 and 9, invention 7, are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the protein or polypeptide of invention 1 can be used in a materially different process, for example, as a product in the manufacture of a conjugate antigen by conjugating to a polysaccharide. The vector of invention 2 could be used in a materially different process, for example, as a coating antigen reagent in an *in vitro* ELISA. The nucleic acid of invention 2 can be used in a materially different process, for example, in the manufacture of a probe reagent for use in a diagnostic kit. The antibody of invention 3 can be used in a materially different process, for example, as an immunogen to raise anti-idotypic antibodies.

Because these inventions are distinct for the reasons given and have acquired a separate

Serial Number 10/091,007
Art Unit: 1645

status in the art as shown by their different classifications/subclassifications and divergent subject matter, and since a search performed for one product would not be co-extensive to the other, restriction for examination purposes as indicated is proper.

- 7) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).
- 8) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).
- 9) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. a message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER